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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/305,738	05/06/99	MOSBACH K	003300-357

HM12/0824

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EXAMINER	
CEPERLEY, M	
ART UNIT	**PAPER NUMBER**
1641	4

DATE MAILED: 08/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/305,738	MOSBACH et al
Examiner	**Group Art Unit**
Mary E. Ceperley	1641

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *27-35* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *27-35* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. The specification must be amended to include a section entitled "Brief Description of the Drawings". "Scheme 1" of page 16 needs to be either inserted at an appropriate location within the body of the specification or presented as a figure.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34 and 35 are rejected under 35 USC 112, first and second paragraphs, as not corresponding with the description of the invention as it is set forth in the specification and as being indefinite for the following reasons.

a. In claim 34, it is unclear what is meant by the term "molecule" as it appears in the term "labeled molecule" since the type of molecule intended is unclear. Page 3, lines 18-27 of the specification indicates that this "labeled molecule" is a tracer i.e. a labeled ***drug*** molecule wherein the "drug" moiety is the same as the "drug molecule" analyte in the serum being assayed. This rejection may be overcome by inserting the word --drug-- between "labeled" and "molecule" wherever this term appears in claim 34.

b. In claim 34, the term "providing a ***fluid*** sample" is inconsistent with the narrower preceding term "assaying a drug molecule in ***serum***" since the term "fluid" is broader than the term "serum".

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosbach (U.S. 5,110,833).

D→102/103

Mosbach discloses artificial antibodies which are of the same composition as those of the instant claims, i.e. they are prepared from a cross linked polymer by molecular imprint polymerization (see col. 3, lines 13-46 and claim 1 of the reference). Mosbach does not specifically require that the antibodies have a particle size of <5 microns, as claimed. However, polymer particle sizes of <5 microns are commonly used in immunoassays and other immunological techniques involving antibodies. Thus, this particular choice of particle size constitutes an obvious variant of a parameter (i.e. particle size) which is routinely modified/optimized in the art and which has not been described as being critical to the practice of

the invention. The features of the dependent claims (e.g. drug analytes) are either specifically described by Mosbach (see col. 3, lines 13-22) or constitute obvious choices of equivalent drug analytes which are routinely assayed by immunological techniques (see col. 3, lines 23-24), as claimed.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by Mosbach et al (U.S. 5,872,198).

Mosbach et al disclose molecularly imprinted polymer beads which are of the same composition as the artificial antibodies of instant claim 27, i.e. they are prepared from a cross linked polymer by molecular imprint polymerization. The particles have a size range of "about 2 to about 100 microns", preferably 2-5 microns, which is inclusive of the size range of instant claim 27 i.e. "less than about five microns". See Mosbach et al, col. 3, lines 26-29 and 43-49. These beads anticipate those of instant claim 27.

9. Claims 27-35 are rejected under 35 USC 103 (a) as obvious over Mosbach et al (U.S. 5,872,198) taken in view of Mosbach (U.S. 5,110,833).

Δ → 102/103 over 1833 above

Mosbach et al disclose molecularly imprinted polymer beads which are of the same composition as the artificial antibodies of the instant claims, i.e. they are prepared from a cross linked polymer by molecular imprint polymerization. The particles have a size range of "about 2 to about 100 microns" which is inclusive of the size range of instant claim 27 i.e. "less than about five microns". Mosbach et al do not specifically describe the drug analytes of the instant claims or the use of the artificial antibodies in immunoassays, as claimed. However, Mosbach discloses that artificial antibodies of this type which are specific for drugs and their use in immunoassays are both well known in the art (see paragraph 6. above). Given the fact that the Mosbach and Mosbach et al references are ***both drawn to the same molecular imprint (artificial antibody) art***, the combination of the teachings of Mosbach et al and Mosbach is considered to render obvious the use of artificial antibodies (molecular imprint polymers) of particle size <5 microns as reagents for drug analyte detection by immunoassay, as claimed. The features of the dependent claims (e.g. particular drug analytes) are either specifically described by Mosbach (see col. 3, lines 13-22) or constitute obvious choices of equivalent drug analytes which are routinely assayed by immunological techniques (see Mosbach, col. 3, lines 23-24).

10. Paliwal et al (U.S. 5,756,717: col. 11, lines 6-21; col. 15, lines 59-67), Domb (U.S. 5,630,978: Example 7), and Mosbach et al (U.S. 5,994,110: col. 10, lines 28-43) are cited to further show the state of the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 17, 2000
Disk: 06/00

Mary E. Ceperley
Primary Examiner
Art Unit 1641